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The Truth Hurts?: FDA Regulation of Truthful Speech

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I. Introduction

One of the more frightening pictures in our society is one of a speaker being silenced, simply by virtue of who the speaker is; yet, the FDA engages in that type of censorship on a regular basis. The FDA censors manufacturer dissemination of truthful information concerning unapproved (off-label) uses of prescription drugs, and does so at the expense of the First Amendment. Nor does the FDA further its mission of protecting the health and safety of the American public through its censorship. In fact, the FDA's rigid policy creates more harm than good. Although off-label drug use can present serious harms, there are more efficient and less constitutionally offensive means to minimize such harms than through the FDA's current regulations.

Parts I and II of this essay will set forth the relevant regulatory scheme and the current rubric for commercial speech jurisprudence. Part III examines the FDA's asserted justifications and rationales for regulating information

pertaining to off-label drug-use. Parts IV and V include a policy analysis of the regulations, and set forth a few alternative solutions. This essay concludes that not only do the FDA regulations violate the First Amendment, they do not make good policy sense. The freedom agencies enjoy in the face of the First Amendment is a serious problem in our society, one exemplified by FDA regulation of manufacturer dissemination of truthful speech concerning off-label uses.

Prior to the 1990's, the FDA's attempts to regulate manufacturer dissemination of scientific and medical information relating to unapproved uses of their drugs remained mostly unnoticed and unchallenged.¹ However, early in the 1990's, the FDA began attempts to regulate not just the dissemination of articles, but also manufacturer sponsorship of continuing medical education (CME) courses.² Around 1992, the FDA also began a concerted effort to regulate the

¹In 1972, the FDA gave notice of a proposed rulemaking pertaining to off-label uses of prescription drugs. According to the proposal, the FDA did not have authority to prohibit the prescription of drugs for off-label use, but did have the authority to regulate the accompanying labeling and information. See *Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration: Notice of Proposed Rule Making*, 37 Fed. Reg. 16503 (August 15, 1972). The *Notice* pointed out that

where a manufacturer or his representative, or any person in the chain of distribution, does anything that directly or indirectly suggests to the physician or the patient that an approved drug may properly be used for unapproved uses for which it is neither labeled nor advertised, that action constitutes a direct violation of the Act and is punishable accordingly...

Id.

²Given its limited scope, this essay will not attempt to address the policy and constitutional concerns raised by the regulation of industry-sponsored CME's. However, it is worth noting that the United States District Court for the District of Columbia has declared that the FDA's attempted regulation was unconstitutional. See *Washington Legal Foundation v. Friedman*, 13 F.Supp.2d 51 (D.D.C. 1998) (issuing an injunction against the Final Guidance on Industry Supported Scientific and Educational Activities, 62 Fed.Reg. 64074 (1997), the Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed. Reg. 52800 (Oct. 8, 1996), and the Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed.Reg. 52800 (Oct. 8, 1996)) (hereinafter *Friedman I*); *Washington Legal Foundation v. Friedman*, 36 F.Supp.2d 16 (D.D.C. 1999) (holding that the 1998 injunction was not limited to the three guidance documents challenged in the case) (hereinafter *Friedman II*); *Washington Legal Foundation v. Friedman*, 36 F.Supp.2d 418 (D.D.C. 1999) (granting

manufacturers' dissemination of scientific and medical literature concerning off-label uses of the manufacturers own products. The original, informal policy of warning manufacturers by letter was eventually compiled and published as the Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data³ and the Guidance for Industry Funded Dissemination of Reference Texts.⁴ Following the finding that these two Guidance Reports were unconstitutional,⁵ as well as the passage of the Food and Drug Administration Modernization Act (and implementing regulations),⁶ the FDA in turn promulgated another, similar attempt to regulate manufacturer dissemination of information pertaining to off-label uses.⁷

In the 1997 FDAMA, Congress undertook one of the first comprehensive reworking of the Food Drug & Cosmetics Act in decades. In response to the threatened expiration of the Prescription Drug User Fee Act of 1992,⁸ Congress, the FDA, and the regulated industries worked together to produce FDAMA. In addition to addressing concerns about the speed of drug approvals, the type of review, and the clinical trial process, Congress also attempted to modify the FDA's regulation of information relating to off-label uses. Specifically, FDAMA tries

to eliminate First Amendment and policy concerns raised by the stringent reg-

summary judgment and issuing permanent injunction with respect to the three guidance documents) (hereinafter *Friedman III*). For an excellent response to the Draft form of the CME regulation, see BAD PRESCRIPTION FOR THE FIRST AMENDMENT: FDA CENSORSHIP OF DRUG ADVERTISING AND PROMOTION (ed. Richard T. Kaplan 1993).

³61 Fed.Reg. 52800 (Oct. 8, 1996).

⁴61 Fed.Reg. 52800 (Oct. 8, 1996).

⁵See *Friedman I*, 13 F.Supp.2d 51; *Friedman II*, 36 F.Supp.2d 16; *Friedman III*, 36 F.Supp.2d 418.

⁶Federal Food, Drug, and Cosmetic Act, § 554(d), as amended, 21 U.S.C.A. §§ 360aaa-3(d).

⁷The new regulations involved 21 U.S.C. §§ 360aaa- 360aaa-6 and the FDA's *Final Rule on the Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices*, 21 C.F.R. Part 99.

⁸101 Stat. 4491 (1992), 21 U.S.C. 379g.

ulation of manufacturer dissemination of information relating to off-label uses of their products.

FDAMA (and its very similar implementing regulations) included several provisions relating to manufacturer dissemination of off-label use information; four in particular proved especially contentious. First, that a manufacturer must submit an advance copy of the information to be disseminated to FDA, as well as any clinical trial information and reports of clinical experience.⁹ Second, that the manufacturer may disseminate off-label use information only if the manufacturer did one of three things: 1) submitted a supplemental application for approval of the off-label use, 2) certified to the FDA that such an application would be forthcoming, or 3) the Secretary made an exemption based on a finding either that the supplemental application would be “economically prohibitive” or would require “unethical studies.”¹⁰ Third, any dissemination carried with it affirmative disclosure obligations, including that a) the off-label use is not FDA approved; b) the manufacturer is paying for the dissemination; c) any author receiving compensation from or having a financial interest in the manufacturer; d) current approved labeling; e) if applicable, that there are other approved products for the use; f) who funded the off-label use study; and g) a bibliography of other scientific articles concerning the off-label use.¹¹ Finally, the manufacturer would be required to prepare and submit (semi-annually) to the FDA lists of the articles and reference publications disseminated as well as the categories of

⁹ See FDAMA § 551(b).

¹⁰ See *id.* at § 554(a).

¹¹ See *id.* at § 551(b).

recipients.¹² The FDA clearly intended the regulations to provide physicians with a more balanced view of the current state of the off-label use, as well as providing an incentive to manufacturers to submit applications for unapproved uses. Unfortunately, the FDA’s attempts to achieve these admirable and legitimate goals come at the expense of the First Amendment and sound policy in general.

II. The Constitutional Framework

The First Amendment, even in the area of so-called “commercial speech,” promotes several important societal values. Briefly stated, a free and open exchange of information is conducive to better decisionmaking,¹³ a free marketplace of ideas (complete with competitive incentives), individual self-realization, autonomy-enhancing,¹⁴ and a more efficient free economic market.¹⁵ In a demo-

¹²See *id* at § 553. See generally 21 U.S.C. § 360aaa; see also Washington Legal Foundation v. Henney, 56 F.Supp.2d 81, 83 (citing Defs.’ Suppl. Memo. at 7-8).

¹³Commentators such as Alexander Meiklejohn originally introduced the idea that speech is essential to representative government and issues affecting “self-government.” See. MEIKLEJOHN, FREE SPEECH AND ITS RELATION TO SELF-GOVERNMENT (1948). Given our reliance on a market economy as an important component of our society, the idea that the First Amendment contributes to better decisionmaking applies in the commercial speech area as well. See Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 765 (1976).

¹⁴As opposed to the instrumental view espoused in the decisionmaking and marketplace of ideas rationale, the autonomy values focus much more on the intrinsic value of the right to free speech. Some authors relying on this value would also extend First Amendment protection to commercial speech. See, e.g., Martin Redish, *The Value of Free Speech*, 130 U.PA.L.REV. 591 (1982) (arguing that instead of a purely utilitarian or instrumental view, the First Amendment is a means to the “much broader value of individual self-realization.”); David A. Strauss, *Persuasion, Autonomy, and Freedom of Expression*, 91 COLUM. L. REV. 334 (1991) (emphasizing the incompatibility of censorship with human autonomy, and the impropriety of paternalism as a ground for interference with speech).

¹⁵Some authors would rely on a combination of all or some of these rationales, as opposed

cratic and free-market society, there are strong utilitarian justifications for more information and for greater protection of speech. In a society that cherishes the individual, there is an inherent value to self-expression and the ability to make decisions for oneself. The regulation of information relating to off-label uses undermines both types of values.

A. The Commercial Speech Category

Since the *Chaplinsky* case, the Supreme Court has accepted the idea that there are certain categories of speech that either merit limited First Amendment protection, or fall completely outside of the Constitution's protection.¹⁶ One such category is "commercial speech," which enjoys less protection than other types of speech. In 1942, the Supreme Court stated broadly in *Valentine v. Chrestensen*¹⁷ that the First Amendment imposed no "restraint on government as respects purely commercial advertising."¹⁸ However, the Supreme Court later made it clear that simply having a commercial motive does not exclude speech from protection.¹⁹ For instance, "movies and books have long enjoyed

to one specific value. See, e.g., LAURENCE TRIBE, *AMERICAN CONSTITUTIONAL LAW* 789 (2d Ed. 1988); Steven Shiffrin, *The First Amendment and Economic Regulation: Away From a General Theory of the First Amendment*, 78 NW.U.L.REV. 1212 (1983).

¹⁶*Chaplinsky v. New Hampshire*, 315 U.S. 568 (1942). In upholding a conviction, the Court described "fighting words" as one of the "classes of speech, the prevention and punishment of which have never been thought to raise any Constitutional problem." *Id.* at 571-72. For an general analysis of the categorization as opposed to balancing approach, see Kathleen M. Sullivan, *The Supreme Court: 1991 Term- Foreword: The Justices of Rules and Standards*, 106 HARV. L. REV. 22 (1992); Kathleen M. Sullivan, *Post-Liberal Judging: The Roles of Categorization and Balancing*, 63 U. COLO. L. REV. 293 (1992).

¹⁷316 U.S. 52 (1942).

¹⁸*Id.* at 54.

¹⁹In *New York Times v. Sullivan*, for instance, the Court rejected the argument that the

First Amendment protections even though they are produced and distributed for profit.”²⁰ As a result, the critical inquiry in cases is often whether the speech is “commercial,” a question that formed a significant portion of the inquiry in challenges to the FDA regulations.²¹ Until the mid-1970’s, regulations infringing upon so-called commercial speech were generally upheld, given the Court’s stance that commercial speech did not enjoy First Amendment protection.²² By contrast, from the time of the 1976 *Virginia Pharmacy* decision, the Supreme Court has made it clear that even speech that does “no more than propose a commercial transaction” is not completely outside First Amendment protection.²³ The initial inquiry, as framed by the Court, was very similar to the inquiry relating to off-label use information. “What is at issue is whether a state may completely suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of the information’s effect upon its disseminators and its recipients.”²⁴ The *Virginia Pharmacy* Court found that the state could not. The Court started with the premise that “[g]eneralizing, society also may have a strong interest in the free flow of commercial information.”²⁵ More specifically

First Amendment did not apply to a “paid ‘commercial’ advertisement.” 376 U.S. 254, 265 (1964).

²⁰GERALD GUNTHER & KATHLEEN M. SULLIVAN, CONSTITUTIONAL LAW 1175 (13th ed. 1997).

²¹See *Friedman I*, 13 F.Supp.2d at 62-66.

²²A comparison of cases such as *Martin v. Struthers* and *Breard v. Alexandria* demonstrates the importance of the “commercial” designation. In *Martin*, the Court held that it was unconstitutional to *apply* a ban on uninvited door-to-door solicitation to Jehovah’s Witnesses. 319 U.S. 141 (1943). In *Breard*, however, the Court found that application of a similar ordinance to magazine subscription solicitors did not violate the First Amendment. 341 U.S. 622 (1951).

²³425 U.S. 748, 759 (1976).

²⁴*Id.* at 773.

²⁵*Id.* at 764.

So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.²⁶

The Court in *Virginia Pharmacy* also explored the idea of solutions other than inhibiting the free flow of information.

There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.²⁷

Even though the current test is the *Central Hudson*,²⁸ the *Virginia Pharmacy* factors have continuing relevance on a policy level. The information on off-label uses is not inherently harmful, and given the existence of alternative remedial schemes (e.g., tort) the assumption should be that scientists in respectable journals will not want to publish harmful information. In addition, as the *Virginia Pharmacy* court indicates, there is an independent value to individual decisionmaking, so long as the individual is informed. The entire goal of limiting restrictions on off-label uses is to increase the flow of available information, thereby enhancing informed decisionmaking between physicians and patients.

Since 1980, courts have applied the four-part *Central Hudson* test to speech deemed commercial. The first determination is whether the speech concerns lawful activity and is not misleading.²⁹ Next, the Court determines whether

²⁶ *Id.* at 765.

²⁷ *Id.* at 770.

²⁸ *Central Hudson Gas v. Public Service Comm'n*, 447 U.S. 557, 566 (1980).

²⁹ *See id.* The Supreme Court has taken a very different approach to defining misleading that has the FDA historically. The Supreme Court has been much more likely to take the

the asserted governmental interest is “substantial.” If so, does the regulation “directly advance[]” the asserted governmental interest. Finally, is the regulation “no[] more extensive than is necessary to serve that interest.”³⁰ On its face, the fourth factor appears to call for a least restrictive means test; however, that prong of the test has suffered from a significant degree of uncertainty. At one point, the Court explicitly stated that the fourth prong is instead a question of narrow tailoring and reasonable fit, not least restrictive means.³¹

On the other hand, in *44 Liquormart* the Supreme Court unanimously struck down a Rhode Island regulation restricting advertising of liquor.³² A plurality of the justices agreed that the regulations should be subject to strict scrutiny, although the majority could agree only that the regulation failed the *Central Hudson* test. For instance, Justice Thomas wrote in concurrence that:

In cases such as this, in which the government’s asserted interest is to keep legal users of a product or services ignorant in order to manipulate their choices in the marketplace, the balancing test adopted in *Central Hudson* should not be applied, in my view. Rather, such an ‘interest’ is per se illegitimate and can no more justify regulation of ‘commercial’ speech than it can justify regulation of ‘noncommercial’ speech....[A]ll attempts to dissuade legal choices by citizens by keeping them ignorant are impermissible.³³

Although he did not command the majority, the breakdown of votes in *44*

Liquormart could indicate a trend toward expanding protection of commercial speech at face value. The FDA, on the other hand, has imposed requirements such as the “fair balance” and “brief summary” rules. Since 1964, the FDA regulations required drug advertisers to maintain “a fair balance” in presenting “a brief summary relating to side effects, contraindications, and effectiveness” of their drug. 29 Fed. Reg. 257 (1964); 21 CFR §§ 1.105(a)-1.105(e) (1964). In effect, the FDA has taken the position that arguably incomplete information can be inherently misleading. For a simple example, the FDA could consider giving the benefits of a drug without the potential side effects to be misleading.

³⁰*Central Hudson*, 447 U.S. at 566.

³¹See *Board of Trustees, State Univ. of New York v. Fox*, 492 U.S. 469, 477-78 (1989).

³²*44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996).

³³*Id.* at 518 (Thomas, J., concurring).

speech.³⁴

*B. Washington Legal Foundation v. Friedman (Friedman I)*³⁵

The FDA regulations of off-label uses have not fared well, even under the commercial speech rubric. Originally, Judge Lamberth of the United States District Court for the District of Columbia assessed the FDA regulations before the Food and Drug Modernization Act of 1997 (“FDAMA”).³⁶ In *Friedman I*, Judge Lamberth found that three FDA regulations failed the *Central Hudson* test.³⁷ Judge Lamberth applied the *Central Hudson* test after finding that the identity of the speaker (in this case the manufacturer, not the researcher) was an important factor in determining that the speech was commercial.³⁸ Interestingly, Judge Lamberth also assessed the potentially misleading *effect* of the information, rather than the information itself,³⁹ conjuring up images of the

³⁴The breakdown of votes was sufficiently complicated to preclude reading the Court’s future intent with any reasonable degree of certainty. Even the narrowest interpretation applying *Central Hudson* included Justice Rehnquist, who had dissented in both *Virginia Pharmacy* and *Central Hudson*. *Id.* at 518.

One potentially important case indicating a narrowing of First Amendment protection, but that has not yet been sufficiently applied to show its significance, is *Glickman v. Wileman Bros.*, 521 U.S. 457 (1997). The majority looked at mandatory fees for generic fruit advertising, and found that speech was not implicated at all. However, there were strong dissents by four members of the court.

³⁵For a comprehensive analysis of *WLF v. Friedman*, see *Comment: The FDA’s Shrinking Place in the Constitutional Universe*. Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998) (unpublished manuscript).

³⁶See *Friedman I*, 13 F.Supp.2d 51.

³⁷*Id.* At issue were the three Guidance documents, discussed *supra* note 1: the Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data (“Reprint Guidance”), Guidance for Industry Funded Dissemination of Reference Texts (“Textbook Guidance”), and Final Guidance on Industry Supported Scientific and Educational Activities (“CME Guidelines”).

³⁸*Id.* at 62.

³⁹Judge Lamberth implied that one reason the speech could be misleading is the absence of

clear and present danger test, which has been rejected with respect to other types of speech.⁴⁰

In reaching the commercial speech question, the District Court also rejected threshold contentions that the regulations concerned conduct as opposed to speech, and that speech by the heavily regulated pharmaceutical industry did not enjoy First Amendment protection.⁴¹ The FDA also made the related argument that because the FDA enjoys the greater power to regulate the pharmaceutical industry in general, the agency also has the authority to regulate related speech. Judge Lamberth, finding that the 44 *Liquormart* Court had overruled the *Posados* holding that the “greater includes the lesser,” also rejected this contention.⁴²

Judge Lamberth then went on to apply the *Central Hudson* test. Importantly, the District Court found that the conduct in question under the first prong was the off-label prescribing.⁴³ Given that the FDA does not explicitly regulate the practice of medicine (discussed in more detail below), off-label prescriptions are not illegal. In finding that the speech was not inherently misleading, the court did discuss the possibility that the FDA could impose re-

a mechanism by which to distribute contrary information. *Id.* at 65. However, as discussed below, the FDA in fact has significant resources for a counter-information campaign, and there do exist private medical and consumer watchdog organizations to provide such contrary information.

⁴⁰See *Brandenburg v. Ohio*, 395 U.S. 444 (altering the *Schenk v. United States*, 249 U.S. 47 (1919) clear and present danger test).

⁴¹See *Friedman I*, 13 F.Supp.2d at 59-61.

⁴²*Id.* at 61 (citing 44 *Liquormart*, 517 U.S. 484; *Posadas de Puerto Rico Assocs v. Tourism Company of Puerto Rico*, 478 U.S. 328 (1986)).

⁴³See *id.* at 66.

quirements to decrease the possibility of misleading speech.⁴⁴ For example, the injunctive relief applied only to certain classes of information, with a focus on the level of expertise and independence of the source.⁴⁵ Under the second prong of *Central Hudson*, the court acknowledged that the government does have a legitimate substantial interest in creating incentives to compel manufacturers to get off-label treatments on-label.⁴⁶

The FDA regulations also directly advanced the substantial interest by creating an incentive to submit new uses to the FDA's pre-market approval process. The real problem for the FDA was that the regulations were "considerably more extensive than necessary to further the substantial government interest."⁴⁷ In Judge Lamberth's words, "the most obvious alternative is full, complete, and unambiguous disclosure by the manufacturer."⁴⁸ In issuing an injunction against certain types of FDA restrictions, the court focused on factors encouraging independent and dependable research. Specifically, Judge Lamberth found that the FDA could not "prohibit, restrict, sanction or otherwise seek to limit" manufacturer dissemination of articles "previously published in a bona fide peer-reviewed professional journal," or reference textbooks (or portions thereof) "published by a bona fide independent publisher and otherwise generally available for sale in bookstores or other distribution channels where similar books are normally available..."⁴⁹

⁴⁴ See *id.* at 68-69.

⁴⁵ See *id.*

⁴⁶ See *id.* at 70-72.

⁴⁷ *Id.* at 73.

⁴⁸ *Id.*

⁴⁹ *Id.* at 74.

In response to a subsequent request to limit the application of the injunction to the pre-FDAMA regulations, Judge Lamberth emphasized that *Friedman I* was intended to apply not just to the actual three guidelines, but to the underlying policies as well.⁵⁰

The Court’s decision and injunction must be read to apply to the underlying policies of the FDA, and not merely to the express provisions of the Guidance Documents, given the history of the policies at issue, which have been expressed in various documents over the years.⁵¹

In so phrasing his response, Judge Lamberth implied that regardless of the iterations of restrictions, the FDA will face a stiff battle when attempting to regulate in this particular area. The District Court went on to invite the parties to submit additional briefing respecting the effect of FDAMA.⁵²

*C. Washington Legal Foundation v. Henney*⁵³

In July of 1999, Judge Lamberth found that the FDAMA implementing regulation on manufacturer dissemination of information pertaining to off-label uses (the *Final Rule on the Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices* (“Final Dissemination Rule”)), violated the First Amendment.⁵⁴ Specifically, Judge Lamberth declined to exempt

⁵⁰See *Friedman II*, 36 F.Supp.2d 16, 18. Judge Lamberth then granted summary judgment and issued a permanent injunction. See *Friedman III*, 36 F.Supp.2d 418.

⁵¹*Id.*

⁵²See *Friedman II*, 36 F.Supp.2d at 19.

⁵³56 F.Supp.2d 81 (D.D.C. 1999).

⁵⁴*Id.* See generally 21 U.S.C. § 360aaa for the relevant statute, as well as the *Final Rule on the Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices*, 21 C.F.R. Part 99. Given the fact that “the FDA regulations issued pursuant to

the FDAMA implementing regulations from the scope of the injunction granted in *Friedman I*.⁵⁵ After disposing of an additional threshold argument presented in the defendant’s supplemental briefing,⁵⁶ the court once again applied the *Central Hudson* test. In finding that the speech was not ‘inherently misleading,’ the court noted that “the defendants themselves admit to the importance of ensuring the availability of such information to physicians and health care providers making prescription and treatment decisions.”⁵⁷ Under the second prong, the court once again dismissed the contention that “ensuring that physicians receive accurate and unbiased information upon which to make prescription decisions” was a sufficiently substantial governmental interest.⁵⁸ In fact, the Judge issued a strongly worded response:

The government, however benign its motivations, simply cannot justify a restriction of truthful nonmisleading speech on the paternalistic assumption that such restriction is necessary to protect the listener from ignorantly or inadvertently misusing the information.... [t]his axiom is particularly powerful where the recipient of information is a sophisticated listener trained extensively in the use of such information— as are the doctors and other health care providers in this case.⁵⁹

The District Court did accept that the FDA’s second justification, that of the FDAMA, while adding some detail to the language of the FDAMA, do not differ materially from the act itself,” the court analyzed the statute and regulation as one. *WLF v. Henney*, 56 F.Supp.2d at n.4.

⁵⁵ *See id.*

⁵⁶ The defendant claimed that “the Court should not apply First Amendment commercial speech scrutiny to the FDAMA because...the act ‘affirmatively permits’ speech so long as it complies with the requirements of the statute.” *Id.* at 85. The court replied strongly that “[t]his is, of course, preposterous. The First Amendment is premised upon the idea that people do not need the government’s permission to engage in truthful, nonmisleading speech about lawful activity.” *Id.* The opinion went on to offer the following example: “the government could not justify a law criminalizing criticism of the government on the theory that such a law would ‘affirmatively permit’ pro-government speech.” *Id.* Accordingly, “[n]either can the FDA escape judicial review of its speech restrictions on the theory that they ‘permit’ speech that complies with the FDA’s wishes.” *Id.* (footnote omitted).

⁵⁷ *Id.*

⁵⁸ *Id.* at 86.

⁵⁹ *Id.*

encouraging manufacturers to submit the off-label uses for approval.⁶⁰

As the court did not accept the government's asserted interest in preventing the dissemination of biased information interest, many of the FDA's requirements were doomed, as they did not advance a substantial and legitimate government interest.⁶¹ The opinion did conclude that one requirement did directly advance the substantial governmental interest in encouraging supplemental drug applications.⁶² This requirement stated that a manufacturer may disseminate off-label use information only if the manufacturer did one of three things: 1) submitted a supplemental application for approval of the off-label use, 2) certified to the FDA that such an application would be forthcoming, 3) the Secretary made an exemption based on a finding either that the supplemental application would be "economically prohibitive" or would require "unethical studies."⁶³ However, the court then found that the FDAMA "amount[ed] to a kind of constitutional blackmail- comply with the statute or sacrifice your First Amendment rights."⁶⁴ The court concluded that "such a gross imposition upon free speech is in clear violation of the First Amendment, and it cannot stand."⁶⁵

D. The Commercial Speech Category, a Problem for the First Amendment

⁶⁰ *See id.*

⁶¹ *Id.*

⁶² The Court rejected the contention that the other FDAMA provisions encouraged additional applications because they made speech more cumbersome. In so doing, the noted that "[t]his argument is immediately suspect because...it restricts constitutionally protected speech as an incentive device." *Id.* at 87 n.7.

⁶³ *Id.* at 86-87.

⁶⁴ *Id.* at 86. It is worth noting here that the court in *WLF v. Henney* combined its analysis of the FDAMA and the implementing regulations, so the opinion applies to the FDAMA itself. *See id.* at n.4.

⁶⁵ *Id.*

As a policy matter, the categorical approach has become increasingly problematic, and “commercial” speech as a category does a disservice by potentially legitimizing the troublesome categorical approach. The traditional presumption under First Amendment jurisprudence is that the government bears the burden of showing the necessity and legitimacy of regulations burdening speech. As a result of the categorical approach, by contrast, certain types of speech fall completely outside the scope of First Amendment protection.⁶⁶ According to the *Chaplinsky* Court, regulation of certain “classes” of speech do not raise any “Constitutional question.”⁶⁷ Once within a categorical exception, the presumption and burden shifted from the government to the individual. Government authority to regulate or even prohibit certain categories of speech was not considered by the post-*Chaplinsky* Supreme Court to be a violation of the First Amendment.⁶⁸

However, as it became more and more difficult to define certain types of speech, and as our societal understanding of the subjective nature of these categorical labels increased, the Supreme Court has moved away from the categorical approach. In areas such as incitement (or fighting words), the Supreme Court has not found speech to be within that category since *Chaplinsky* itself.⁶⁹ From

⁶⁶Examples include “fighting words” and “obscenity.”

⁶⁷315 U.S. 568, 571-72.

⁶⁸*See id.*

⁶⁹GUNTHER & SULLIVAN, *supra* note 20, at 1078. One commentator has in fact proclaimed that the fighting words doctrine is “nothing more than a quaint remnant of an earlier morality that has no place in a democratic society dedicated to the principle of free expression”. Stephen W. Gard, *Fighting Words as Free Speech*, 58 WASH. U.L.Q. 531, 535-36 (1980).

a subjective point of view, some of the speech certainly had the effect of inciting (if not always the intent), but the Supreme Court has greatly limited the categories. The area of obscenity provides a particularly illuminating example: one man's filth is another man's art. The idea of "lewd" or "profane" speech as unprotected has also become increasingly limited.⁷⁰ In addition, given the interplay between civil rights and speech, the Supreme Court has had to acknowledge the crucial role of speech in informing and activating individuals.⁷¹ One category that has survived, with astonishing vitality in fact, has been that of the commercial speech, as defined by the *Central Hudson* test and its progeny. However, the categorical approach does not work in the commercial speech either, so the Supreme Court should continue the trend of extending protection to all speech, regardless of its previous classification. Although the Supreme Court has attempted to narrowly define commercial speech, it has become progressively more difficult for the courts to determine what qualifies as commercial speech.⁷² An additional problem that occurs in much greater relief in the commercial speech area, is that the dispositive question is often who is speaking, and not what the speaker is saying. As Judge Lamberth noted, there is no question that the speech at issue in the off-label use cases would undoubtedly enjoy

⁷⁰The Court in *Cohen v. California* found that a jacket emblazoned with the phrase "F*** the Draft" was protected speech, and essentially shifted the burden to the "listener" to avert their eyes. 403 U.S. 91 (1971). An unacceptable solution was to prohibit the speech in the first instance.

⁷¹By the same token, recent speech codes seek to address the fact that some views of civil rights demand regulation of offensive and hateful speech. See, e.g., MATSUDA ET AL., WORDS THAT WOUND: CRITICAL RACE THEORY, ASSAULTIVE SPEECH, AND THE FIRST AMENDMENT (1993).

⁷²For instance, in *Friedman I*, the court spent a considerable amount of time determining whether the speech was commercial or "pure." *Friedman I*, 13 F.Supp.2d at 66-65.

protection if it was disseminated by anyone except the manufacturer.⁷³ Even worse than a content-based censorship, the Supreme Court is now engaged in censorship based on the speaker's identity. In fact, the Supreme Court recently acknowledged that "[e]ven under the degree of scrutiny that we have applied in commercial speech cases, decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment."⁷⁴ The commercial speech doctrine, based as it is on the outdated categorical approach, ignores the fact that although the motive for the manufacturer could be economic, the listener (either the patient or the doctor) does not have an economic motive, but does have a right to the free flow of information.

III. Justifications and Rationales

A. *The Potential Harms*

The off-label use of prescription drugs does potentially lead to several serious harms. First, although the drugs have been approved, the FDA approves these only drugs for specific uses. As a result, the fact of approval might be irrelevant to the safety or efficacy of an off-label use. The testing system is based on the requirement that the manufacturer seek approval for particular uses for

⁷³ "It is beyond dispute that when considered outside of the context of manufacturer promotion of their drug products, CME seminars, peer-reviewed medical journal articles and commercially-available medical textbooks merit the highest degree of constitutional protection." *Id.* at 62.

⁷⁴ *Greater New Orleans Broad. Assoc. v. United States*, —U.S. —, —, 119 S.Ct. 1923, 1935 (1999).

the drugs. As a result, the test groups will exhibit certain characteristics, and the participating individuals could closely resemble one another in dispositive ways. Therefore, the general applicability of such studies are inherently limited. To take an example, for a cancer drug, the test group will share certain characteristics, and more importantly, researchers will control for discrete, specific variables. Researchers could be looking for particular genetic predisposition to cancer, to interaction with other types of treatment, and will be focused on cancer specifically. To transfer the results to a different group, perhaps those suffering from acne, would undermine the applicability of the original study. In addition, unapproved uses could step outside of proportional risk.⁷⁵ The FDA could approve a potentially dangerous drug to fight a lethal disease, but not to fight a skin condition.⁷⁶

Second, reliance on an ineffective off-label drug use could preclude or discourage the use of a more effective drug. Nor is this concern limited to the area of off-label uses.⁷⁷ In the case of off-label uses, because the drug does not have to go through the rigorous testing process, which tests both safe *and* effective, there is a greater potential for error. The end result could be that patients are prescribed an ineffective drug. Patients could then ignore continuing or addi-

⁷⁵One example of an off-label use was the prescription of powerful heart drugs, approved to control severe arrhythmia, for cases of mild arrhythmia, which unfortunately provoked heart attacks. See Tom Abate, *Americans to be Guinea Pigs in Debate Over Off-Label Drug Uses/Results to determine whether speed or safety should be top priority*, SAN FRANCISCO CHRONICLE, 1999 WL 2694411 (August 30, 1999). Although the risks did not become clear until later, it is possible that the FDA would still have approved the drug in the face of a health threat the magnitude of severe (but not mild) arrhythmia.

⁷⁶The counter-argument, explored in greater depth below, is that patients should be making the cost-benefit analysis themselves in any event.

⁷⁷For example, one alleged problem with dietary supplements, or less regulated medical devices, is that patients rely on these “cures” to the exclusion of effective remedies.

tional symptoms, thinking that they are currently being treated, when in fact they are not.

A contributing factor increasing the potential harm of off-label uses (but one that arguably undermines the need for regulation) is that there is generally less information generally available to consumer/patients about prescription drugs as opposed to OTC drugs. Ironically, this lack of information is due in large part to the strongly restrictive regulation of prescription drug advertising and labeling.⁷⁸ The currently available sources of information (advertisements, physician package inserts, and the *Physician's Desk Reference*, to name a few) do not give adequate information relating to off-label uses. The FDA's regulations restricting manufacturers' ability to allude to off-label uses in the advertisements or package inserts has had the perverse effect of keeping patients uninformed. As a result, it is even more important that doctors be more informed about potential new uses for drugs.

The numerous arguments in favor of direct-to-consumer advertising also argue in favor of more information to doctors. There are several situations in which it is preferable for more information to be available: for previously untreatable conditions, for more effective treatments, for potentially embarrassing conditions, and given that manufacturers often cannot advertise (especially off-

⁷⁸The interaction of the broad definition of labeling with the strict labeling regulations, including required and prohibited information, means that many otherwise available channels of information are limited or precluded. Congress did re-examine the broad labeling requirements, but made only modest adjustments. FDAMA § 126. Although the FDA claims not to be regulating the information as labeling per se, information only falls outside of the reach of labeling if it meets the requirements set forth in FDAMA. *See id.* at § 557(b).

label uses) at least the doctors would have access to more information, if nothing else as a trigger about a current patient. Of course, the fact that there might be less information generally available could militate against allowing more information only to doctors, in that it could further reduce the patient's role in treatment. The general dearth of information could also eliminate the patient as a check on an incorrect or hurried doctor, especially in the age of the HMO and capitation.

A more general argument, and one that Judge Lamberth in particular addresses, is the problem of fraud prevention.⁷⁹ Across the board, the FDA fights against fraud, in the form of economic adulteration, misbranding, misleading labeling, and more. One part of the agency's mission is to fight fraud and deception. The FDA has determined that sending out articles touting off-label uses are "inherently misleading,"⁸⁰ a determination is entirely in keeping with the FDA's general regulation of drug labeling and advertising. The combined effect of the broad definition of labeling⁸¹ and the "fair balance" and "brief summary" requirements has meant that the FDA enjoyed wide discretion and power over manufacturer's speech.⁸² As a result, the FDA has been very successful at requiring manufacturers to provide more complete information, meaning the potential negatives at well. Not content with product warnings for inherently dangerous drugs, the FDA has a laundry list of requirements for the "brief sum-

⁷⁹ See *Friedman I*, 13 F.Supp.2d at 65-69.

⁸⁰ See *id.*

⁸¹ See *Kordel v. United States*, 335 U.S. 345 (1948).

⁸² See generally 21 C.F.R. § 202.1

mary.” With the attached articles and other promotional activities, the FDA has determined that the source of the information, as well as the alleged lack of balance, are inherently misleading. However, this is not necessarily a sound premise, especially in light of the intended audience. This area is different from direct-to-consumer advertising or the OTC market in that a physician must prescribe the medicine. The information is not aimed at the traditional “ignorant, unthinking, and credulous” segment of the population.⁸³ Instead, the information is aimed at the highly educated physicians, who have reputational and liability concerns of their own.⁸⁴

B. The Constitutional Argument

The FDA also asserted two particularly interesting legal arguments: that the regulations are aimed at conduct not speech, and even if the regulations do effect speech, the pharmaceutical industry is so heavily regulated that the manufacturers should not expect or enjoy traditional First Amendment protection. The idea that the regulations are aimed at conduct as opposed to speech are not completely without merit, especially in light of the analysis in *Friedman*

I. Although Judge Lamberth rejected this conduct argument, in applying the

⁸³ “[I]t must be noted that the manufacturers are not seeking to distribute this information to the general consumer public, who likely lack the knowledge or sophistication necessary to make informed choices on the efficacy of prescription drugs.” *Friedman I*, 13 F.Supp.2d at 70.

⁸⁴ Judge Lamberth emphasized the effect the intended audience has on the FDA’s asserted rationales. *See id.*

Central Hudson test, he did rely heavily on the finding that the regulated activity was the actual prescribing of off-label uses.⁸⁵ This reliance appears to create a tension with the predicate finding that the regulations concerned speech. The heavily regulated industry argument is one that the FDA has successfully advanced in the Fourth Amendment context.⁸⁶ However, Judge Lamberth rejected this argument as well, relying primarily on precedents dismissing the argument. There is also a very logical reason to distinguish the Fourth and First Amendments with respect to this argument. As Fourth Amendment jurisprudence has developed, one important factor has been a reasonable expectation of privacy.⁸⁷ In a heavily regulated industry, or location, the expectation of privacy cannot reasonably be as high as in a home for example. As a result, the Supreme Court has found that the Fourth Amendment places less of a restriction on government conduct with respect to drivers, and the food industry, to name just two examples. However, the First Amendment is not so dependent upon a contextual analysis. Finally, there is a textual argument: the Fourth Amendment contains the modifier “unreasonable,” while the First Amendment on its fact is a blanket prohibition of government restrictions.

IV. As Applied: The Policy Arguments

A. Regulating the Practice of Medicine

⁸⁵ See *id.* at 66.

⁸⁶ See *U.S. v. Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532 (8th Cir. 1981).

⁸⁷ See *id.*

In addition to specific examples of restricting the availability of or information about certain types of treatment, the FDA’s current regulation of off-label uses also invokes other, more general themes and potential harms. At one level, the FDA is coming perilously close to regulating the practice of medicine. Although never explicitly precluded from doing so, the FDA does not regulate the practice of medicine (in the sense of what approved drug a doctor may prescribe for what purpose), and it does not make good policy sense for the FDA to attempt to do so.⁸⁸ One traditional argument in favor of delegation to agencies, and for increasing agency authority in general, is that of expertise. However, in the area of medicine, it is simply not the case that in general an FDA bureaucrat will have greater expertise than even a general practitioner. In addition, the FDA employees are too far removed from individual interaction to accurately calculate cost-benefit analysis for everyone. In the field of treating specific ailments, a general, one size fits all rule will be both over-and-underinclusive. The doctor is in a far superior position to make that analysis, especially in conjunction with their patient.

⁸⁸Since the 1972 *Notice of Proposed Rule Making, Legal Status of Approved Labeling for Prescription Drugs: Prescribing for Uses Unapproved by the Food and Drug Administration*, the FDA has arguably conceded that the current regulatory scheme does not extend authority to the FDA to regulate the practice of medicine, at least with respect to prescribing off-label uses. 37 Fed. Reg. 16503 (August 15, 1972). As the FDA explained

In *United States v. Phelps Dodge Mercantile Co.*, 157 F.2d 453 (9th Cir. 1946), the court held that violations while products are held for sale after interstate shipment did not come within the jurisdiction of the Act. As a result, Congress [amended the Act with respect to adulteration and misbranding]. The 1948 amendment did not, however, also extend the reach of the new drug provisions of the Act.

Id. As the *Notice* continued, “[t]his interpretation of the Act is consistent with congressional intent as indicated in the legislative history of the 138 Act and the drug amendments of 1962.” *Id.* Interestingly, with respect to medical devices, section 214 of FDAMA explicitly states that FDAMA is not intended to interfere with traditional physician authority. By the same token, the medical profession fiercely guards its own notions of being a self-regulated profession. *See, e.g.*, PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* (1982).

Society has also already determined that we have a certain level of trust in doctors. We heavily regulate the process of becoming a doctor, and there exist a wide range of tort remedies against negligent or tortious conduct by doctors. At a certain point, we acknowledged that doctors are better situated than FDA employees to “practice medicine.” In addition, Congress has agreed with that societal assessment: the FDA is arguably not empowered to regulate the actual practice of medicine. In the current regime, the FDA effects the practice of medicine not just through the obvious prohibition on unapproved drugs, but by limiting the free flow of information to doctors. In a practice that resembles a prior restraint, the FDA has determined that the most appropriate method is to cut off the flow of information, rather than to engage in a counterattack of information.⁸⁹ Traditionally in First Amendment jurisprudence this type of preemptive action has been highly disfavored, and there is no reason why there should be an exception in the communication of truthful information from manufacturers to doctors.

B. The Paradigmatic Slippery Slope

⁸⁹ Although the Supreme Court has upheld prior restraints of commercial speech, the same policy arguments against prior restraints in other areas also apply in the commercial speech context. John Milton wrote in protest against the practice as early as *AREOPAGITICA- A SPEECH FOR THE LIBERTY OF UNLICENSED PRINTING* (1664). As William Blackstone described it, the major danger in subjecting the press, for example, to “the restrictive power of a licenser [is] to subject all freedom of sentiment to the prejudices of one man, and make him the arbitrary and infallible judge of all controverted points in learning, religion, and government.” 4 Blackstone, *COMMENTARIES ON THE LAWS OF ENGLAND* *151-52. In the case of the FDA, the pre-market approval process allows one individual in an administrative agency to have a vast impact on the course of progress in science: what is currently “good science.”

At a broader level, a strong slippery slope argument exists supporting the need to rein in the FDA. The FDA has traditionally shown itself very willing to take highly aggressive stances on contentious issues, even to the point of endangering the Constitution. There is a strong need to send a message to the FDA that there are certain limits, and more specifically, that magic words and recitation cannot justify active censorship. The FDA consistently relies on its mantra that its actions are in the interest of public health and safety. However, the FBI can also make a strong case that those words exactly capture its mission as well, but we still apply the Fourth Amendment to FBI actions.⁹⁰ At the very least, explicit Constitutional prohibitions such as the First Amendment should serve as a presumption shifting device. In which case, the FDA would bear the burden of proving that each regulation is justified in the face of the Constitution, and more importantly, that some type of least restrictive means is applied.⁹¹

C. The Capture Problem

One particularly troublesome possibility, and one which is pervasive in the administrative state, is the idea of agency capture.⁹² To take an example of how this could work in general in the FDA context would be in determining

⁹⁰In the context of the FDA, the court has concluded that the industry's Fourth Amendment rights are much more limited, given its inclusion in the "class of closely-regulated businesses." *U.S. v. Jamieson-McKames Pharmaceuticals, Inc.* 651 F.2d 532 (8th Cir. 1981).

⁹¹*Cf.* FREDERICK SCHAUER, *FREE SPEECH: A PHILOSOPHICAL ENQUIRY* (1982) (setting forth a negative theory of the First Amendment, based on government's inherent inability to regulate speech); Frederick Schauer, *The Second-Best First Amendment*, 31 WM & MARY L. REV. 1 (1989).

⁹²*See generally*, George J. Steigler, *The Theory of Economic Regulation*, 2 BELL J. ECON & MGMT SCI. 3 (1971). (introducing the concept of what we now call agency capture).

the definition of a standard food. If the Florida Orange Growers have 10% fruit juice and 90% water, but their competitors use only 5% juice, the Florida Orange Growers have a strong incentive to set the standard level at 10%. One of two things could happen. Either the agency could be “captured” in the sense of setting the level at 10%, thereby “leveling the playing field” at a level too high for smaller players, or, as happened in the infamous peanut butter incident, the battle over setting the standard could take up to twenty years to resolve. The amount of agency resources expended in the peanut butter example, quite possibly to prevent fraud, could not possibly justify the incremental benefit to the consumer.

One scenario some have argued represents industry capture of the FDA revolves around the renewal of the Prescription Drug User Fee Act (PDUFA)⁹³ and FDAMA. The 1992 PDUFA had a five-year term, at which point the Act would expire in the absence of affirmative congressional action. The impending expiration of PDUFA provided the impetus for passing FDAMA; given the increasing FDA reliance on the user fees, the industry was able to gain certain concessions industry had been wanting for some time. Although most would argue that FDAMA represents a positive for all parties concerned, it is also true that with the user fee, the regulated industry now has a certain amount of leverage over the agency itself. In addition to the actual provisions of FDAMA, the FDA has also bound itself to relatively stringent performance goals for areas such as application reviews and drug development times.

⁹³106 Stat. 4491 (1992), 21 U.S.C. 379g.

Playing this agency capture idea out in the context of off-label drug use, there are several possible explanations for why certain portions of the “industry” could actually support strong regulations. First, there is the possibility, such as in the aspirin example, that an OTC drug could have broad therapeutic effects in an area currently cornered by the prescription drug makers. In the aspirin example, the pharmaceuticals would have to compete not only with the OTC drugmakers, but also the generic drug market, at potentially great expense.⁹⁴ A second possible interaction would be between the dietary supplement industry and the pharmaceutical drug industry. Unfortunately, in both scenarios, it is quite possibly the consumer/patient who is ultimately paying the price for turf wars. Doctors are deprived of information about possibly cheaper unapproved alternatives while huge pharmaceutical drug manufacturers guard their ultimate profits. Although this scenario is purely hypothetical, it does demonstrate that established segments of the industry could have the means by which to take advantage of the conservative nature of the FDA.

D. Resource Allocation

The issue of resource allocation is one of the most pressing for any agency. In this case, the FDA in particular is strongly limited by its funding. The FDA has only one billion dollars to regulate food, drugs, and cosmetics. As a result,

⁹⁴In a related case, the Federal Trade Commission and several states have brought suit against the increasingly powerful generic drug manufacturers, alleging antitrust violations. See *FTC v. Mylan Laboratories, Inc.*, 62 F.Supp.2d 25 (D.D.C., 1999).

the FDA must be especially careful to choose the most harmful areas, and to concentrate resources there. For example, active fraud creates a huge concern, particularly in the drug area. In the food area, given the recent outbreaks of lethal food contamination, the FDA should perhaps focus there. Instead, the FDA has chosen to simultaneously offend the First Amendment and basic notions of triage by regulating information given to *doctors* about off-label uses of previously approved drugs. The drugs at issue have already been approved as safe and effective.⁹⁵ Therefore, it makes much less sense for the FDA to focus resources on this area that poses on average a less extreme risk to the public health and safety.

E. The Structural Flaws

1. Missing Checks and Balances

One of the most problematic aspects of the FDA in particular is that the FDA fulfills the dual role of regulating both the approval process as well as the advertising process. As a result, repeat player companies not only do not have an incentive to challenge FDA actions, but the industry in fact suffers from a serious disincentive.⁹⁶ As a result, recent challenges do not involve industry members such as Merck or Upjohn, instead, public interest organizations such

⁹⁵It is undoubtedly the case that the context could be very different between the approved and off-label uses. The possible harms such as differences in the test group and the preclusion of a more effective remedy are discussed more thoroughly *supra* Part IIIA.

⁹⁶One commentator has given this situation the very apt label of “structural censorship.” See *Comment*, *supra* note 35, at.

as the Washington Legal Foundation have taken up the fight to protect the First Amendment.⁹⁷ The FDA wields incredible power through the pre-market approval process. Companies that spend billions of dollars in hopes of approval will be strongly discouraged from irritating the FDA in any way. Whether or not there has empirically been retaliation is immaterial- the mere threat of retaliation creates a sufficient disincentive to industry challenge. The FDA's current dual function of approval and advertising regulation also creates at least the appearance of impropriety and images of power-hungry bureaucrats preventing legitimate First Amendment challenge not through overt actions, but through the reservoir of power.

Another important effect of this dual function and disincentive is the substantial limit on the role of the judiciary as a check on agency action. Even in light of the judiciary's permissive attitude toward agencies⁹⁸ there are certain lines that the courts would presumably draw in the sand. The First Amendment might be a good place for the judiciary to start limiting agency authority. Regardless of the argument of judicial abdication of its checking function on the agencies, the judiciary has not even had the opportunity to apply checks.

Another check one might presume existed would be Congress itself, but Congress has shown itself to be remarkably willing to initiate the legislation undermining

⁹⁷Other recent cases include plaintiffs such as the Nutritional Health Alliance and the National Council for Improved Health. *See* Nutritional Health Alliance v. Shalala, 953 F. Supp. 526 (S.D.N.Y. 1997), *affirmed in part, and vacated and dismissed in part*, 144 F.3d 220 (2d Cir. 1998); National Council for Improved Health v. Shalala, 122 F.3d 878 (10th Cir. 1997). The latter case demonstrates another problem with the dual hat disincentive: the Tenth Circuit dismissed the suit for lack of standing.

⁹⁸For example, in the wake of *Chevron*, the courts have taken an extremely deferential view toward agency construction of the enabling statutes. *See* *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *Young v. Community Nutrition Institute*, 476 U.S. 974 (applying *Chevron* to the FDA).

the First Amendment. Depending on the political climate, Congress could determine that its interests would be best served by offering restrictive advertising legislation, rather than attacking the product itself. Two recent examples of this phenomenon include tobacco and alcohol. As off-label drug use is neither a clear benefit nor danger, Congress has apparently determined that allowing the FDA to regulate the advertising rather than the products themselves is preferable.⁹⁹

2. *The FDA's Conservative Nature*

The FDA, like many agencies, has an inherently conservative nature.¹⁰⁰ The agency's high profile leads to a greater reluctance to approve a potentially harmful drug, as opposed to "merely" delaying approval. In addition, the FDA could see more harm in allowing the promotion of off-label uses than in not having the drug available. Meaning, if requiring pre-approval of additional uses would be the end result of the FDA's restrictions on advertising, that would not be the disfavored result for the FDA. The possible harms of not having a different treatment available would be outweighed in the mind of the FDA by the potential harm of allowing an off-label use. In addition to the possible harms to the public health and safety, like any other agency or institution, the FDA also has

⁹⁹See also, Richard T. Kaplar, *The FDA and the First Amendment in BAD PRESCRIPTION*, *supra* note 2.

¹⁰⁰One of the seminal articles introducing the concepts of false negatives and positives, and advocating a more conservative approach in the context of the EPA, is Talbot Page, *A Generic View of Toxic Chemicals and Similar Risks*, 7 *ECOLOGY L.Q.* 207 (1978). With respect to the FDA, one interesting article examining the effects of a conservative approach is Steven R. Salbu's *The FDA and Public Access to New Drugs: Appropriate Levels of Scrutiny in the Wake of HIV, AIDS, and the Diet Drug Debacle*, 79 *B.U.L.REV.* 93 (1999).

reputational harms.

One systemic reason for the FDA's reluctance to allow greater off-label use is its reluctance to assess Type-II harms. In other words, in the FDA's cost-benefit calculus, the harm from the lack of a drug is less likely to be considered, if such potential harm is even quantifiable.¹⁰¹ To take an example, aspirin has a wide off-label use for heart disease prevention. The Type II analysis would consider those lives lost to heart disease because individuals did not have access to the potential curative effects of aspirin. However, in the FDA's defense, that number would be very hard to assess, if at all possible. A pervasive problem with Type II analysis is that they often end up resembling attempts to prove a negative.

In all fairness, it is perhaps not reasonable to expect that the FDA would provide a check on itself. In other areas, such as the Fourth Amendment and Due Process claims, not only has the FDA determined that the public health and safety rationale was a sufficiently compelling rationale, but the courts have consistently agreed.¹⁰² However, these cases provide a greater lesson: we cannot count on the FDA to adequately weigh valid First Amendment concerns.

¹⁰¹See, e.g., *Salbu*, supra note 94 for a case study relating to FDA approval of protease inhibitors and the fight against HIV.

¹⁰²See, e.g., *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950).

F. Not an Option

One seemingly obvious response is that manufacturers should simply submit the off-label uses for approval; unfortunately, the current approval system makes that option a disfavored one. As the legislative history to FDAMA indicates, not only is there not an incentive to submit supplemental applications, there may in fact be disincentives. Even the supplemental applications could represent a time-consuming and expensive process. Section 403 of FDAMA represents an attempt to encourage submission of supplemental applications, but its effects have yet to be seen. So one net effect of the need for an expensive approval process for additional uses has been to discourage additional uses and research into additional uses of already approved drugs. It is also possible that the FDA's regulations create an incentive to go to the black market, as opposed to waiting for drugs made more expensive by the pre-market or supplemental approval process.

V. The Solutions

A. *One hat per agency*

One obvious solution to this problem would be to return regulation over advertising to the Federal Trade Commission, where it was until relatively recently.¹⁰³ The FTC already regulates the advertising aspect of several areas

¹⁰³Under the 1938 Wheeler-Lea Act the FTC had authority to regulate drug advertising. 15 U.S.C. 55(a).

of FDA control, and putting prescription drug advertising in the FTC would eliminate the “structural censorship” currently embedded in the FDA. Another at least partial solution would be to reduce the definition of labeling, which currently blurs the line between advertising and labeling, and protected and non-protected speech.

B. The Existing Layers of Protection

The FDA does not stand alone in wanting to protect the American public. There are at least three other safety nets for each individual: the doctor, the manufacturer, private organizations, and the individual themselves.¹⁰⁴ The off-label uses at issue in this paper relate only to prescription drugs: meaning, a doctor must prescribe the drugs. The doctor is by definition a certified practitioner, in tort law in fact, the doctor is the learned intermediary. We already acknowledge that doctors have a special role, and allowing the greater flow of information to doctors should have the positive effect of increasing communication between doctors and patients as well. In this area, is that one size does not fit all. Here, in consultation with her doctor, and individual can make an informed decision, assessing the level of risk that she personally is willing to take. An attempt to make a risk assessment, possibly with respect to life-threatening diseases, at the national level, simply does not make sense. Although styled as

¹⁰⁴Interestingly, FDAMA § 403(d) requires the Secretary of HHS to develop policies to encourage collaboration between the government and professional medical and scientific organizations and societies.

a prophylactic rule, the FDA’s policy does not take into account the Type II harms that occur when otherwise effective remedies are not publicized or available.

The manufacturer also has an important stake in the entire process. Given the availability of tort remedies, in some cases to the point of manufacturer bankruptcy, the manufacturer also has an incentive to limit publication of off-label uses to only those that are sufficiently tested and safe.¹⁰⁵ In addition, there are private organizations that play an important role in informing and protecting the public. Associations and institutes such as the American Medical Association and the National Cancer Institute provide just two alternatives to strict FDA regulations. Given the fact that a significant percentage of cancer treatments are off-label¹⁰⁶ (although the number is somewhat skewed by the fact that the FDA doesn’t approve compound drugs in any event), the NCI already plays a significant role.

Finally, the scientific community as a whole has an important stake, especially in the current FDA scheme. Publications must appear in “bona fide” publications, such as peer-reviewed journals.¹⁰⁷ The apparent rationales behind the current emphasis on peer-reviewed journals include a higher reputational stake for better-known journals, as well as a more-deserved assumption that the information in such journals are reliable, and reflect better scientific methods and

¹⁰⁵The breast implants provide particularly high profile example of tort remedy (although not necessarily related to off-label use). As for off-label uses, testimony in *WLF v. Henney* indicated that manufacturers could potentially face liability stemming from off-label uses. See *Guinea Pigs*, *supra* note 75.

¹⁰⁶See *id.*

¹⁰⁷According to the *Friedman I* and *WLF v. Henney* decisions, the injunction applies only to those articles and sources meeting certain criteria. See generally *supra* note 49 and accompanying text.

studies. Scientists must put their names on the research, and their peers must sanction its publication in order to give the research even the minimum of credibility. Taken in conjunction with the liability-adverse nature of the doctors and manufacturers, there is a conservative trend to the non-FDA protections as well. Each level has not only their reputation but a potentially disastrous lawsuit at stake. The FDA's apparent premise that the situation pits the susceptible individual against the money-hungry, evil manufacturing industry is simply not an accurate portrayal.

C. Fight Fire with Fire

One time-honored maxim in the First Amendment realm is that the solution to speech with which one disagrees is more speech, not to silence those with whom you disagree. Given the resources at the government's disposal, this maxim applies particularly well when it is the government that seeks to silence. In the case of off-label uses, the FDA has several methods by which it can promote consumer understanding of the potential harms of off-label use. Not only has the FDA already proved itself very adept in the information age (for example, its extremely comprehensive website) but one should never underestimate the power of the press. Press releases and notification of the press of potential abuses of the system by the huge, faceless, pharmaceutical industry could be front-page news.

D. Trust the Citizen

Another, related, First Amendment concept is that in general the First Amendment favors dangers of misuse over dangers of suppression. This argument is hard to make given the potentially lethal effects of misuse in this case. However, an argument in favor of First Amendment protection is that regardless of the risk factor, the FDA should eschew paternalism and allow the physician and patient to make an informed decision together, instead of eliminating a potentially helpful drug. The cost-benefit analysis in these cases goes on a two distinct levels: whether any off-label use promotion should ever reach the physician, and whether the patient should follow a particular off-label treatment. The First Amendment weighs heavily on the side of allowing the information in general, for utilitarian and autonomy-enhancing reasons. As for the individual case, it should be for the patient and physician to assess the amount of risk the patient is willing to assume in the hopes of a cure.

VI. Conclusion

The FDA's regulation of manufacturer dissemination of truthful information concerning unapproved uses directly violates the First Amendment. More importantly, the regulations violate the spirit and values imbued in the First

Amendment. Finally, the FDA's censorship at best does not contribute to its mission of protecting the health and safety of the American public, and at worst actually undermines its own mission. There are sufficient protections in place for the patient/consumer, so the FDA should respect the First Amendment and its own institutional mission and cease regulating manufacturer dissemination of truthful speech.